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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	24

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/765,739	Applicant(s) LAWTON ET AL.	
	Examiner Vanessa L. Ford	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34 and 39-42* is/are pending in the application.

4a) Of the above claim(s) *1-20 and 25-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-24 and 39-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

FINAL ACTION

1. This Office Action is responsive to Applicant's response filed July 28, 2003. Claims 21 and 23 have been amended. Claims 39-42 have been added. Claims 35-38 have been cancelled.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Rejections Withdrawn

3. In view of Applicant's amendment and Response, the following rejections are withdrawn:

a) Rejection of claims 21-24 and 35-38 under 35 U.S.C. 112, first paragraph, pages 3-5, paragraph 5 of the previous Office action.

b) Rejection of claims 21-24 and 35-38 under 35 U.S.C. 112, first paragraph, pages 6-8, paragraph 6 of the previous Office action.

Rejections Maintained

4. The rejection under 35 U.S.C. 102(a) is maintained for claims newly presented claims 39-42 for the reasons set forth in pages 9-12, paragraph 7 of the previous Office Action.

The rejection was on the grounds that Waner et al teach the use of a device (i.e. a clinic ELISA test kit). Waner et al teach that *Ehrlichia canis* IgG antibody titers of serum samples were determined by using a commercial ELISA test kit containing plastic combs sensitized with *E. canis* antigen. Waner et al teach that the sera to be tested was incubated with the comb (containing antigen dots). Waner et al teach that after washing away unbound antibodies the comb were allowed to react with goat anti-dog IgG alkaline phosphatase conjugate.

Waner et al teach that bound antibodies were detected with a precipitating chromate, 5-bromo-4chloro-3-indolyl phosphate and nitro-blue tetrazolium. The polypeptide sequence contained on the plastic comb (i.e. device) would be inherent in the teachings of the prior art. It is well known in the art to include instructions for using polypeptides for the identification of an *Ehrlichia* infection in a mammal in a diagnostic kit. The instructions for performing various immunoassays (i.e. western blot, reversible flow chromatographic binding assay, enzyme linked immunosorbent assay or indirect immunofluorescense assay) are well known in the art. The device of Waner, et al appears to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's device with the device of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the device of the prior art does not possess the same material structural and functional characteristics of the claimed device). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that Waner et al do not teach or suggest a device containing one or more polypeptides consisting of SEQ ID Nos:1-7 and substitutions variants thereof that specifically bind to an anti-*Ehrlichia* antibody. Applicant urges that Waner et al do not teach the use of any types of *E. chaffeenis* polypeptides in a device. Applicant urges that SEQ ID Nos: 3-7 of the present invention are *E. chaffeensis* derived polypeptides and therefore cannot be anticipated by Waner et al. Applicant urges that Waner et al do not teach, suggest or inherently disclose each and every element of claims.

Applicant's arguments filed July 28 2003 have been fully considered but they are not persuasive. The claims are drawn to a device containing one or more polypeptides selected from the group consisting of the polypeptides shown in SEQ ID Nos:3-7 and amino acid substitutions variants thereof that bind specifically to an anti-*Ehrlichia* antibody. It is the Examiner's position that there is nothing on the record to show that the claimed device differs the device of the

prior art. Waner et al teach the use of a device (i.e. a clinic ELISA test kit) comprising *Ehrlichia* antigen. The claimed invention encompass variants of SEQ ID Nos:3-7, one skilled in the art could reasonably conclude that the *E. canis* polypeptide of the prior art is an amino acid substitution variant of one of the polypeptides as set forth in SEQ ID Nos:3-7 since, Applicant has provided no side-by-side comparison to show that the claimed polypeptide differs from the *Ehrlichia* polypeptide of the prior art. It should be noted that the claimed device contains polypeptides that detect *Ehrlichia* infection wherein the infection is caused by *Ehrlichia canis* or *Ehrlichia chaffeenis* and that the polypeptides detect the presence of *Ehrlichia* antibodies not that the claimed polypeptides are from *Ehrlichia canis* or *Ehrlichia chaffeenis*. Therefore, Waner et al anticipate the claimed invention.

5. The rejection under 35 U.S.C. 102(b) maintained for claims newly presented claims 39-42 for the reasons set forth in pages 12-14, paragraph 8 of the previous Office Action.

The rejection was on the grounds that Cadman et al teach a device (i.e. a cross dot blot apparatus), nitrocellulose paper was coated with *E. canis* antigen. Cadman et al teach that 0.7 μg of protein in TBS was use per dot. Cadman et al teach that test sera was incubated with the antigen (dots on nitrocellulose paper). Cadman et al teach that the bound antibody was detected with peroxidase-labeled goat anti-dog IgG and 4-chloronaphthol. The polypeptide sequence contained on the nitrocellulose membrane (i.e. device) would be inherent in the teachings of the prior art. It is well known in the art to include instructions for using polypeptides for the identification of an *Ehrlichia* infection in a mammal in a diagnostic kit. The instructions for performing various immunoassays (i.e. western blot, reversible flow chromatographic binding assay, enzyme linked immunosorbent assay or indirect immunofluorescense assay) are well known in

the art. The device of Cadman, et al appears to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's device with the device of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the device of the prior art does not possess the same material structural and functional characteristics of the claimed device). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that the claims have been amended to recite devices containing one or more isolated polypeptides consisting of SEQ ID Nos: 1-7 and amino acid substitution variants of SEQ ID Nos:1-7 that specifically bind to an anti-*Ehrlichia* antibody. Applicant urges that Cadman et al do not teach or suggest a device containing one or more polypeptides consisting of SEQ ID Nos:1-7 and substitution variants thereof that specifically bind to an anti-*Ehrlichia* antibody.

Applicant's arguments filed July 28, 2003 have been fully considered but they are not persuasive. The claims are drawn to a device containing one or more polypeptides selected from the group consisting of the polypeptides shown in SEQ ID Nos:3-7 and amino acid substitutions variants thereof. It is the Examiner's position that there is nothing on the record to show that the teaching of the prior art do not anticipate the claimed invention. Cadman et al teach an indirect fluorescent assay (IFA) which is the recommended diagnostic test for *E. canis* infection, and has shown to be both sensitive and specific (page 362, 1st column). The claimed invention encompass variants of SEQ ID NOs: 3-7, therefore one skilled in the art could reasonably conclude that the *E. canis*

polypeptide of the prior is an amino acid substitution variant of one of the polypeptides as set forth in SEQ ID NOs:3-7, since Applicant has provided no side-by-side comparison to show: that the device of the prior art differs from the device of the claimed invention. It should be noted that the claimed device contains polypeptides that detect *Ehrlichia* infection wherein the infection is caused by *Ehrlichia canis* or *Ehrlichia chaffeenis* and that the polypeptides detect the presence of *Ehrlichia* antibodies not that the claimed polypeptides are from *Ehrlichia canis* or *Ehrlichia chaffeenis*. Therefore, Cadman et al anticipate the claimed invention.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 39-42 are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 39-42 is indefinite because it recites" a polypeptide shown in SEQ ID Nos:1-7". It is unclear as to what the Applicant is referring?

7. Claims 39-42 (in particular, claim 41) are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 41 is indefinite because it is unclear as to whether the Applicant is claiming a product or process. Clarification is required.

8. Claims 39-42 (in particular, claim 41) are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 41 is indefinite because it recites "under conditions". It is unclear as to what the Applicant is referring?

9. Claim 21 is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim is indefinite because it recites" amino acid substitution variants". It is unclear as to what the Applicant is referring?

The following rejection is maintained because the claims recite "amino acid substitution variants thereof the specifically bind to an anti-*Ehrlichia* antibody" which the Examiner is viewing as any amino acid substitution variant that has sequence identity to any of SEQ ID Nos. 1-7.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 21-24 are rejected under 35 U.S.C. 102(b) as anticipated Rikihisia et al *(WO99/13720, published March 25, 1999).*

Claims 21-24 are drawn to a device that containing one or more polypeptides consisting of SEQ ID Nos:1-7 and amino acid substitution variants thereof that specifically bind to an anti-*Ehrlichia* antibody.

Rikihisia et al teach devices such as columns, plastic dishes and membranes that contain the *Ehrlichia* polypeptides and peptide of the invention for using in serodiagnosing ehrlichiosis in mammals (see the Abstract and page 11). Rikihisia et al teach an amino acid variant of SEQ ID NO:7 has 85% identity to SEQ ID NO:7 (see Figure 19B). Rikihisia et al anticipates the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's device with the device of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the device of the prior art does not possess the same material structural and functional characteristics of the claimed device). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Status of Claims

11. No claims allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Biotechnology Patent Examiner
November 3, 2003

MARK NAVARRO
PRIMARY EXAMINER